Exhibit 20

CONTAINS CONFIDENTIAL BUSINESS INFORMATION
SUBJECT TO PROTECTIVE ORDER

UNITED STATES INTERNATIONAL TRADE COMMISSION
WASHINGTON, DC

Before the Honorable Clark S. Cheney
Administrative Law Judge

In the Matter of

CERTAIN TOBACCO HEATING ARTICLES AND COMPONENTS THEREOF

Investigation No. 337-TA-1199

REBUTTAL EXPERT REPORT OF STACY EHRLICH

RELATING TO THE PUBLIC INTEREST

Stacy Ehrlich

October 23, 2020

disagree with Complainants' assertion that Eclipse serves as an adequate substitute for IQOS®, as that statement is undermined by the vastly divergent FDA authorizations that each has received.

B. ENDS Products Are Not Adequate Substitutes for IQOS®

112. It appears that Complainants rely on ENDS products as the primary substitute for IQOS®. From a regulatory perspective, these, too, are not adequate substitutes.

113. As noted above, under the FFDCA, new tobacco products (i.e., non-grandfathered products) may not legally be marketed without premarket authorization. Accordingly, all deemed new tobacco products on the market without FDA authorization, including all ENDS products, are technically illegally marketed. As Health and Human Services (HHS) Secretary Alex Azar stated, "HHS is taking a comprehensive, aggressive approach to enforcing the law passed by Congress, under which no e-cigarettes are currently on the market legally."[132]

114. However, under FDA's current compliance policy, certain ENDS products are permitted to remain on the market so long as they are the subject of PMTAs filed by September 9, 2020.[133] Significantly, that enforcement discretion policy applies only to ENDS products that were on the market on August 8, 2016, have not been modified since that date, and are not flavored cartridge-based ENDS products (except for tobacco- and menthol-flavored products). Those ENDS products not covered by the compliance policy are subject to enforcement action.[134]

---

[132] 1199_RESP00010611.

[133] *See* 1199_RESP50000269-0279.

[134] *See* Final Rule, Deeming Tobacco Products to be Subject to the Federal Food, Drug, and Cosmetic Act, as Amended by the Family Smoking Prevention and Tobacco Control Act; Restrictions on the Sale and Distribution of Tobacco Products and Required Warning Statements for Tobacco Products (Deeming Rule), 81 Fed. Reg. 29,011 (May 10, 2016), https://www.govinfo.gov/content/pkg/FR-2016-05-10/pdf/2016-10685.pdf; 1199_RESP00016448-59; 1199_RESP00014254-67; 1199_RESP00014118-69.

115. Most PMTAs for ENDS products were submitted on September 9 or in the months leading up to that deadline. For example, Complainants submitted PMTAs in October 2019 for Vuse Solo, in April 2020 for Vuse Vibe and Vuse Ciro, and in September 2020 for Vuse Alto.[135]

116. Many ENDS product manufacturers could not or did not file PMTAs by the September 9, 2020, deadline.[136] Thus, after September 9, the ENDS market in the United States narrowed.[137] Indeed, it is likely that thousands of products are currently subject to FDA enforcement action, potentially shrinking the ENDS market by magnitudes.[138]

117. With regard to premarket submissions (PMTAs, SE reports, and SE exemption requests) that FDA did receive for deemed products, FDA has not released the number of submitters or their names. Sources, however, have indicated that there are over 400 million deemed products listed with FDA.[139]

118. Accordingly, and contrary to the Clissold Report, even assuming that the Agency was fully staffed and ready, it is highly likely to take substantially longer than 12 months to review most of those submissions.[140] Indeed, FDA itself has said that "the likelihood of FDA reviewing all of these applications during the one-year review period is low, given that this would be an unprecedented number of applications and several orders of magnitude greater than anything the

[135] 1199_RESP00016064-65; 1199_RESP00016066-68; 1199_RESP00016069-70; 1199_RESP00016082-85.

[136] 1199_RESP00014302-05.

[137] *See id.*

[138] *See* 1199_RESP00014297-305; 1199_RESP00014222-29; 199_RESP00014462.

[139] *See* 1199_RESP00016450.

[140] *See* Clissold Rep. ¶¶ 32-34.

Agency has experienced."[141] The Agency has also stated that "[a]lthough CTP has greatly expanded its reviewing capacity and is developing well-defined, consistent and transparent review processes for all phases of premarket review, there are limits to these resources considering we may receive applications for several millions of products."[142]

119. Further, it is impossible to predict FDA's determinations regarding these ENDS PMTAs. PMTA authorizations should never be assumed, particularly because: (a) no e-cigarette has obtained PMTA authorization; and (b) the threshold for the APPH determination may change over time.[143] Indeed, some in the industry are skeptical that any e-cigarette will be authorized. For example, former FDA Commissioner David Kessler has stated that he does not believe FDA will allow e-cigarettes to remain on the market. Indeed, "Dr. Kessler said he wouldn't bet on any e-cigarettes surviving the FDA review."[144]

120. Mr. Clissold states that "there is no reason to believe that the PMTAs will not be authorized" for Complainants' Vuse Solo and Vuse Vibe products."[145] I disagree. A PMTA is a complex, voluminous submission. Any number of issues could arise that would frustrate PMTA authorization, even for the most high-quality and well-supported PMTAs. Indeed, as stated above, FDA has never granted PMTA authorization for any ENDS product, so it remains unclear to the

---

[141] Mitch Zeller, Director of FDA's CTP, Perspective: FDA's Preparations for the September 9 Submission Deadline (Aug. 31, 2020), https://www.fda.gov/tobacco-products/ctp-newsroom/perspective-fdas-preparations-september-9-submission-deadline?utm_source=Eloqua&utm_medium=email&utm_term=stratcomms&utm_content=blog&utm_campaign=CTP%20News%3A%20Sept.%209%20Perspective%20-%2083120.

[142] *Id.*

[143] Proposed Rule, Premarket Tobacco Product Applications and Recordkeeping Requirements, 84 Fed. Reg. 50,566, 50,618 (Sept. 25, 2019), https://www.govinfo.gov/content/pkg/FR-2019-09-25/pdf/2019-20315.pdf.

[144] 1199_RESP00014222-229.

[145] Clissold Rep. ¶ 31.

DOCKET ALARM

Explore Litigation Insights

Docket Alarm provides insights to develop a more informed litigation strategy and the peace of mind of knowing you're on top of things.

Real-Time Litigation Alerts

Keep your litigation team up-to-date with **real-time alerts** and advanced team management tools built for the enterprise, all while greatly reducing PACER spend.

Our comprehensive service means we can handle Federal, State, and Administrative courts across the country.

Advanced Docket Research

With over 230 million records, Docket Alarm's cloud-native docket research platform finds what other services can't. Coverage includes Federal, State, plus PTAB, TTAB, ITC and NLRB decisions, all in one place.

Identify arguments that have been successful in the past with full text, pinpoint searching. Link to case law cited within any court document via Fastcase.

Analytics At Your Fingertips

Learn what happened the last time a particular judge, opposing counsel or company faced cases similar to yours.

Advanced out-of-the-box PTAB and TTAB analytics are always at your fingertips.

API

Docket Alarm offers a powerful API (application programming interface) to developers that want to integrate case filings into their apps.

LAW FIRMS
Build custom dashboards for your attorneys and clients with live data direct from the court.

Automate many repetitive legal tasks like conflict checks, document management, and marketing.

FINANCIAL INSTITUTIONS
Litigation and bankruptcy checks for companies and debtors.

E-DISCOVERY AND LEGAL VENDORS
Sync your system to PACER to automate legal marketing.